In conclusion, this study demonstrates that it is possible to treat patients with ABF using an endovascular approach and that the results compare favorably with open surgical repair. Patients tolerated the procedure well, and hemoptysis resolved in all 7 patients. There were no deaths, no episodes of paraplegia, and no endoprosthesis infections. All patients are still alive and there have been no reinterventions. Careful preoperative planning is essential for optimal results when patients are being considered for endovascular repair, especially with regards to vascular access considerations. In our cohort, duration and type of postoperative antibiotics does not appear to correlate with freedom from graft infection. Although endovascular technologies are emerging for the treatment of many types of aortic pathologies, significant questions relating to this therapeutic modality are yet to be resolved including long-term device durability, improved long-term patient outcomes, and economic concerns of increased device cost and expenses related to long-term graft surveillance with CT. Additional investigation and continued graft surveillance are critical to help determine the future role of endovascular technologies.

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Discussion

Dr Craig Miller *(Stanford, Calif).* Thank you, Dr Gelfand and Dr Hawkins. Grayson, that was a very nice presentation that we've come to expect from you.

This is the third report from the Arizona Heart Institute on endovascular treatment of aortotracheal fistulas. Before you got there, there was a report in 2002 with 2 cases. In your large total experience reported this year in the Annals you had 4, and now you have taken us up to 7. You pointed out in the paper that there are 36 cases in the literature and now with 3 more additional, so 39, with an overall mortality rate of 8%, which is pretty darn good considering that a lot of these patients need reoperations and have had previous grafts and whatnot. I think that is very encouraging. The question, therefore, is not can it be done. You and others and we have shown that it can be done, but how effective and how

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durable is it for what can be a devastatingly bad situation? And here I think you have provided some very good news with your follow-up: 43 ± 29 months going out to 6 years, no late deaths, no late infections. It's almost too good to believe, but it is good news and it is very promising and we look forward to more follow-up.

I would like to turn to something that you've already broached and that's the legal and the ethical issues at foot here. You've shown us very clearly the amount of work that Dr Diethrich and the institution had to go through to get a physician-sponsored individual investigator device exemption (IDE) from the Food and Drug Administration. We have also done that, and that allowed you to treat these patients, who would otherwise not have qualified for any of the commercial IDEs. There now are a couple high-risk IDEs that cover this but they are few in number. I want to caution the audience that if you go home and try this, if you are Gore TAG certified, it is going to be off label for an aortobronchial or for an aortoesophageal fistula or even a dissection. It is going to be off label, and you have to be very, very aware that if something doesn't go perfectly well, you don't have a leg to stand on medicolegally in court. The lawyers are out there just waiting for this, and there have been all too many examples already—an abdominal aortic stent graft or a home-brew stent graft or a commercial stent graft used for aortic dissection, for example—where something bad happened, and you just don't have a leg to stand on legally unless you have an institutional physician-sponsored IDE like you do. That brings me to, what are you doing now? Is your physician-sponsored IDE still current, and do you enroll them in that today just to cover yourselves? That's the first question, easy one.

Dr G.H. Wheatley *(Phoenix, Ariz).* Yes. We applied for, and successfully received, an extension and continuation of that protocol. Patients who are being treated with aneurysms were originally included in the protocol, but now that it is Food and Drug Administration approved for aneurysms; those patients are not enrolled in the protocol, and so the protocol now only includes off-label uses in the high-risk surgical patients.

Dr Miller. So right now, you are shut down until the Food and Drug Administration rules on your extension application?

Dr Wheatley. No, it's been approved, and we have been continuously enrolling patients without interruption.

Dr Miller. Oh, it's been renewed and extended. Okay. So you're being judicious and that's important for those of you who might see one of these desperately ill patients roll in some Friday night, because even though you are trying to save their lives, the estate of the family may not see it that way later on.

Okay, 7 cases now. Three were aneurysms, 3 were false aneurysms, and 1 traumatic case. Your slide—I'm glad you showed what happened to the sac with the serial CT scans thereafter. That was one of my questions and that information I assume will now be in the paper. You had 8 patients on that slide, not 7. Can you explain where that eighth flyer got in there? Second, could you elaborate on what happened with the patient with 1 traumatic tear, who had had a previous stent graft? Was it elsewhere? Was it your place? And why that 1 created the complication? And third, I was a little surprised to see that you did not have any giant aortic penetrating ulcers, atherosclerotic ulcers, which can cause an aortotracheal fistula. Any comments there?

Dr Wheatley. Yes. Thank you, Dr Miller, for your comments and certainly thank you for your comments regarding the manuscript and we greatly appreciate your insight.

In terms of the eighth one, that was not included in the graph. It was on the label but it wasn't there. If you count the actual lines, there were only 7. It was a benefit of PowerPoint presentations.

Interesting case, I agree. I think that we need to be very cognizant, and this is 1 of the first that I have been aware of where a patient was 3 years out from a prior ELG repair of a transection. This patient was badly injured. He had motor vehicle accident, liver laceration, and brain injury and was hemodynamically unstable, that's why he was treated with an endoluminal graft, because of his instability and very significant injury, but did well. Three years later he came back with an area distal to that ELG, which was an ulcerative lesion—no real penetrating ulcer, but there is communication right at the distal end of the graft, perhaps maybe because the graft is eroding. The patient did not have aneurysmal disease. Maybe there are some long-term consequences of the ELGs that we are not seeing, but certainly I think that this highlights that we need to be very scrupulous in following these patients, and perhaps it may be a long-term complication of ELG repair in traumatic transections.

Dr Miller. But it wasn't frankly eroded through to the outside.

Dr Wheatley. No, there was just a communication there that perhaps may have been related to the graft.

Dr Miller. And it probably wasn't atherosclerotic disease because this patient sounds like the typical trauma victim—young, healthy, tiny normal aorta and no insurance, right?

Dr Wheatley. Yes, sir.

Dr Miller. You purposely covered the left subclavian once without embolizing it or doing a transposition. You, of course, are setting yourself up for a type 2 leak and we all know that. Some of us have done it. No leak occurred in that patient. What is your current practice? Do you leave a patent left subclavian transmitting endotension to the sac?

Dr Wheatley. We do. We just reported at (ISMICS) 2 weeks ago, our complete 360-patient experience with covering the left subclavian. We cover the left subclavian approximately a third of the time and only needed a bypass in a few patients out of those patients that had covered. If we do see a retrograde type 2 leak from the subclavian, we will then embolize it using a retrograde approach from the brachial, but we manage that usually expectantly. We will usually see that if it is a type 2 endoleak, it is a minor procedure to come back and embolize the subclavian. If there is continued sac growth, it is something that we can always do later, but it is not an emergency need to treat that.

Dr Miller. That's a good answer and probably the right posture, but it is a vexing problem because of the strokes occurring acutely when the left subclavian is covered. I won't go off on a tangent to ask you how you decide when to revascularize it in advance and when not.

Finally, your topic is "Have we gone too far?" and you're pushing the envelope. Let me take you 1 step further. How many aortoesophageal fistulas have you covered with a stent graft, which we have done, but I think we are kidding ourselves and this is futile therapy. What is your experience down in Phoenix?

Dr Wheatley. I agree and that's why I did not include these in the paper. It would be a natural fit to talk about aortoesophageal

fistulas but we have covered 3, and 2 out of 3 have gotten infected. I really don't think that is a good approach, and that's why I did not break these patients out, but really I don't think that should be even tried.

Dr Miller. Got reinfected and died like a dog run over in the street.

Dr Wheatley. Yes, sir.

Dr Miller. Yeah, I'm afraid we echo that. Thank you for coming to the Western Thoracic.

Dr Wheatley. Thank you.

Dr Robert Cerfolio *(Birmingham, Ala.).* I had 2 questions but we only have time for just 1. If you were going to cover a tracheal fistula with an aortic graft, do you now recommend that you put in a graft long enough that you go past or distal to the carina? My concern would be that the distal end of that stent is going to erode into either the left main stem or the carina unless you go past it. Is this your recommendation now?

Dr Wheatley. Yes.